UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,087	04/21/2000	Joseph R. Byrum	16517.132/38-21 (15786)B	4196

7590 02/12/2009

Monsanto Company
Lawrence M Lavin Jr
800 N Linbergh Boulevard
Mailzone N2NB
St Louis, MO 63167

EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
02/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/552,087	BYRUM, JOSEPH R.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-7,9,10 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-7,9,10 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/08 has been entered.

2. Claims 3, 5-7, 9, 10 and 12-20 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. Instant SEQ ID NO: 1 was disclosed as SEQ ID NO: 141338 in application 09/521640 and as SEQ ID NO: 5 in application 09/421106, therefore the instant claims are granted priority to at least 10/15/99. The presence of the sequence in the provisional application was not determined as there was no intervening reference, and as there are thousands of sequences in the provisional application and there is no reasonable way to search the application.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3, 5-7, 9-10, and 12-20 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Rejected claims 3, 5-7, and 9-10 are drawn to plant host cells and transgenic plants that comprise a construct having a promoter, which is linked to a structural nucleic acid molecule that comprises SEQ ID NO: 1 or the complement thereof which encodes a protein or peptide, which is also linked to a 3' non-translated sequence that functions in said cell to cause termination of transcription.

Claims 12-20 are drawn to substantially purified nucleic acid molecules that comprise instant SEQ ID NO: 1 or a nucleic acid sequence that is related to instant SEQ ID NO: 1 by a percent identity. Thus the claims encompass SEQ ID NO: 1 and many, many variants of the sequence.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use.

A well-established utility is defined as a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. The instant host cells and transgenic plants do not have a well established utility because the art does not teach any

utility for the instantly claimed host cells and transgenic plants that is specific, substantial, and credible.

The specification discloses a number of general utilities for the nucleic acids disclosed herein. For example, the specification generally discloses that these nucleic acids are useful in genetic mapping studies (p. 35), physical mapping (p. 43), contig mapping (p. 46), comparative mapping (p. 49-56), the identification of polymorphisms (p. 49-56), monitoring expression (p. 56), locating regions of identity by descent between individuals (p. 58), isolating clones (p. 59), microarray based methods (p. 60), direct site mutagenesis (p. 60), transformation (p. 62-80), in cosuppression (p. 80), to reduce gene function (p. 82), and as antibodies (p. 83). None of these asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequences being claimed.

The instant specification herein discusses transformation of cells and plants in general (p. 62-80), but does not discuss these methodologies with regard to SEQ ID NO: 1 in particular. The specification in table 1 sets forth that the protein encoded by instant SEQ ID NO: 1 has 50% identity with a putative POL3 protein from Arabidopsis, but the specification does not assert a utility for SEQ ID NO: 1 or the protein encoded by SEQ ID NO: 1 based on this homology. The fact that SEQ ID NO: 1 encodes a polypeptide that has homology to a "putative" protein suggests that the functionality of the Arabidopsis protein has not been confirmed. Thus, further experimentation would be required to reasonably confirm the identity of the protein both for Arabidopsis and for Glycine max proteins. Beyond that, further experimentation would still be required to establish a real world utility for such a protein.

The specification teaches that nucleic acid molecules and fragments thereof may be employed as genetic markers (p. 35 and following). Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities, and this is particularly the case with regard to correlation with phenotypic traits or genetic mapping of phenotypic traits. The specification has not demonstrated that instant SEQ ID NO: 1 is related to any particular phenotypic trait, nor has it provided any specific suggestion or discussion of any trait SEQ ID NO: 1 might be related to.

The specification suggests that the claimed nucleic acids may be used in transformation to express any polypeptide that is encoded by the transformed sequence (p. 62 and following). No specific function of the polypeptide encoded by SEQ ID NO: 1 has been provided. The specification has provided no information as to what effect the expression of SEQ ID NO: 1 in a transgenic plant cell or plant would have on the plant. The suggestion that instant SEQ ID NO: 1 can be used to transform plants is an invitation to do further research to determine what effect the sequence might have on plants, or what product is produced upon expression of the encoded polypeptide, if one is encoded.

Claims 3, 5-6, 7, 9, and 10, are drawn to transformed plant cells and transgenic plants that have a construct which contains instant SEQ ID NO: 1 or its complement within a "structural nucleic acid molecule" that encodes a "protein or peptide." Thus, these claims suggest that SEQ ID NO: 1 is being included in the host cells and transgenic plants of claim 3, 5-6, 7, 9, and 10 for its functionality as a "structural nucleic acid." This is not considered a substantial utility because further experimentation would be required to reasonably confirm that

SEQ ID NO: 1, or its complement, encode a polypeptide which has a specific, substantial and credible utility.

The specification does not provide any guidance as to the use of SEQ ID NO: 1, its complement or fragments thereof as structural genes or of the encoded polypeptides, other than a very limited reference to the fact that a polypeptide encoded by SEQ ID NO: 1 has identity with a putative POL3 protein. The specification teaches at page 101 that a peptide or protein encoded by instant SEQ ID NO: 1 has 50% identity with a putative POL3 protein from Arabidopsis thaliana. The examiner was not able to confirm this result with a sequence search. However, a sequence search did reveal a sequence disclosed post-filing of this application that has 40.5% with instant SEQ ID NO: 1 identity to a POL3-like gene from *Phaseolus coccineus*, and that this identity occurs over a portion of the gene that is within the portion encoding the translated protein (see attached alignment and further explanation). This post-filing finding, however, was not present in the specification at the time the invention was made, nor would it have been available to one of ordinary skill in the art at the time the invention was made, as the record was not in the database at that time.

Instant SEQ ID NO: 1 is a nucleic acid sequence, but no guidance is given in the specification as to what strand or frame of the nucleic acid sequence would encode any useful peptide. Results of translation of SEQ ID NO: 1 in all possible frames are included with this office action, and it appears that applicant's alignment is with the 3'5' frame 3 encoded polypeptide fragment, although each frame of SEQ ID NO: 1 encodes peptides of some length. Clearly the frame on which Applicant's remarks focuses is the longest encoded polypeptide,

though it does not represent a complete open reading frame (i.e. there is no initiation codon nor a stop codon).

In remarks filed 11/21/08, attorney argument provides that an alignment of a peptide encoded by SEQ ID NO: 1 with the peptide represented in the NCBI database as GI: 4063760. The alignment shows a portion of a putative protein encoded by SEQ ID NO: 1 with a portion of the prior art sequence. There are sixteen amino acids in the polypeptide encoded by SEQ ID NO: 1 that are not present in the alignment. Further, the prior art sequence that the translation of SEQ ID NO: 1 is aligned to is actually a 1,215 amino acid sequence. The portion represented in the alignment is 113 amino acids- less than ten percent of the totality of the putative POL3 protein. So, the alignment shows that a portion of the encoded polypeptide (about 88%) has 50% identity to a portion (about 9%) of a prior art sequence whose actual identity or function had not yet been determined. It appears that at best, applicant has established that the claimed nucleic acid encodes a polypeptide that shares a motif with a polypeptide that may or may not be a POL3 protein. There is no teaching or discussion in the specification as to whether this portion of the protein would have any particular function, nor is there any evidence on the record to this point. This disclosure does not provide sufficient information to support any substantial utility because further experimentation would be required to reasonably confirm that instant SEQ ID NO: 1 encodes a polypeptide that has any activity at all in common with the prior art molecule to which it has some identity or to any other POL3 molecule.

It is noted that the record on which applicant relies- NCBI record having accession AAC98467 has subsequently been removed from the NCBI database. When the sequence contained therein (represented in the NCBI database as GI: 4063760) was searched against the

NCBI current database, a record containing the same exact sequence identified the polypeptide as a putative retroelement integrase (see search results enclosed with this office action). Thus, it is evident that at the time of filing, the identification of the molecule in the prior art as a "putative POL3 protein" was not a definitive teaching of even the function of the prior art molecule, and such a teaching still does not appear to exist.

The specification also suggests that SEQ ID NO: 1 may be a promoter or part of a promoter. In order to use the claimed invention in view of this disclosure, one would first have to confirm that either SEQ ID NO: 1 or its complement is in fact a promoter, then determine which fragments are also promoters. There is no evidence on the record to point one to the conclusion that the instantly disclosed sequence is or contains a promoter rather than an intron or a coding sequence, both of which are also suggested as possibilities for SEQ ID NO: 1. The sequence search did not identify any sequences with which instant SEQ ID NO: 1 had identity to any promoter.

Even if one were to assume that SEQ ID NO: 1 contained or was a "promoter," one would have to determine the type of promotion conferred by SEQ ID NO: 1, that is, one would have to determine if the promotion is tissue specific or constitutive, for example, or if it is an inducible promoter, and under what circumstances it is induced or repressed in order to make use of the claimed host cells or plants. Without knowing the conditions under which the promoter could be used one would not know how to use the invention. Each of these determinations is highly unpredictable, from the determination as to whether or not SEQ ID NO: 1 or its complement is in fact a promoter to the determination of the type of promoter it may be to the determination of fragments of the promoter that confer promotion activity. There has been no

specific assertion that in fact SEQ ID NO: 1 is a promoter, aside from the claims. The specification generally suggests that all of the sequences disclosed in the application might be promoter molecules (p. 16), but the specification also generally suggests that all of these molecules may comprise introns and coding sequences (p. 24 and 29). Thus, the teachings of the specification themselves, by providing a number of different potential and conflicting descriptions of SEQ ID NO: 1 provide reason to question whether the sequence in fact comprises a promoter, a partial promoter, an exon or an intron or some combination of these. The specification has not provided any further guidance as to the use of SEQ ID NO: 1 as a promoter or its use in any other capacity. Thus, it is left to one attempting to make and use the claimed products to determine which instant SEQ ID NO: 1 actually is and how it can be used within the constructs claimed. Even given the choice between the suggestion that SEQ ID NO: 1 comprises a promoter or a partial promoter, the specification does not provide any guidance or suggestion as to which is the case for SEQ ID NO: 1. This is an important distinction since the entire functioning of a promoter is entirely sequence specific. For example, if SEQ ID NO: 1 contained only a partial promoter, it is highly unpredictable as to whether or not that partial promoter would function to promote production of an mRNA or which part of SEQ ID NO: 1 is in fact the "promoting" part since one cannot simply look at SEQ ID NO: 1 and identify these regions by any disclosed sequence characteristics, and since the function of a promoter is highly sequence specific. Or, if SEQ ID NO: 1 contains a regulatory element, it is highly unpredictable how that element would function in view of the fact that there are hundreds of possible regulatory functions known, and there is no known way to predict if one of these is attributable to instant SEQ ID NO: 1. The instant specification provides a seven page listing of possible functions that

any potential regulatory element contained within the disclosed sequences might have (pages 17-23). Each function would warrant use in a different type of system for expression under different circumstances to achieve an effect specific to the regulatory element. For example, the specification makes reference to oxygen responsive elements, light regulatory elements, and elements responsive to gibberellin. In order to make the claimed invention, one would have to undertake enormous amounts of experimentation to discover if in fact SEQ ID NO: 1 is a promoter or comprises a promoter or a regulatory element, as suggested by the claims and also suggested by the specification, or if SEQ ID NO: 1 contains a structural gene as also suggested by the specification, or if SEQ ID NO: 1 comprises an intron or an intron/exon boundary as also suggested by the specification.

Considering then, the state of the prior art, instant SEQ ID NO: 1 is a novel sequence. A sequence search by the examiner in a variety of nucleic acid databases did not identify any sequence in the prior art with greater than 29% identity over the full length of SEQ ID NO: 1. For example, GenBank AF147259 (13 August 1999) provides the sequence of an A. thaliana BAC, and nucleotides 46185-46519 of this sequence have 29% identity with instant SEQ ID NO: 1. This however is an uncharacterized portion of nucleic acid, and even if the homology were exact would not provide any further guidance as to whether instant SEQ ID NO: 1 contains a promoter or promoter elements, or an intron, or a coding sequence.

Given all of these considerations, the use of instant SEQ ID NO: 1 as a promoter is not a specific or substantial utility since further experimentation would be required to confirm that in fact SEQ ID NO: 1 has the ability to cause the production of an mRNA molecule and the conditions under which such activity occurs. Thus, no utility has been described for the

transformed plant cells and transgenic plants comprising SEQ ID NO: 1 wherein SEQ ID NO: 1 is within the construct as a promoter.

It has not been demonstrated that SEQ ID NO: 1 has any utility as a marker for a specific phenotypic trait. After further research, a specific and substantial credible utility might be found for the claimed cells and plants. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's invention is incomplete.

In the instant case, the specification has provided a wide variety of general guidance that any of the over twenty thousand disclosed sequences may be promoters, coding sequences or introns. The specification has suggested that any of these may be useful for a wide variety of purposes, some of which conflict with one another. For example, if SEQ ID NO: 1 is a promoter or contains a promoter, it is not a coding portion of a gene. If SEQ ID NO: 1 is a promoter, than it would not be an expressed sequence so it could not be used to monitor expression of genes via a microarray (as suggested on page 56). The instant claims are limited to instant SEQ ID NO: 1, and some of these require that SEQ ID NO: 1 comprised within a structural nucleic acid molecule that encodes a protein or peptide. However, these claims do not remove the entirely general disclosure of the specification which suggests a wide variety of functions and uses for all of the disclosed sequences, but no specific and substantial utility for any one sequence, including instant SEQ ID NO: 1.

The facts in this case are very similar to the facts in In re Fisher (CAFC, 04-1465, 9/7/2005). In both applications, a general disclosure is given to support the disclosure of a nucleic acid whose particular function is not disclosed. The court found that none of the utilities generally suggested for the claimed nucleic acids and compositions in the Fisher case (as a

molecular marker, measuring expression, source for primers, identifying polymorphisms, isolating primers, controlling protein expression, or searching for genes in other plants) was enough to overcome the utility requirement. The instant case is similar in that the specification provides merely hypothetical possibilities for uses for the claimed invention. The court has ruled that these are not sufficient to provide a specific and substantial utility to the claimed invention.

As noted by Brenner v. Manson, 383 U.S. 519, 535-536 (1996), and quoted in In re Fisher, "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing…a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed cells and plants such that another non-asserted utility would be well established for the compounds.

For these reasons, the claimed nucleic acids, host cells and transgenic plants are not supported by either a specific and substantial asserted utility or a well established utility. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Claim Rejections - 35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5-7, 9-10, and 12-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidenced in the discussions *supra*, each of these factors have been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Claim Rejections - 35 USC § 112

6. Claims 3, 5, 6, 7, 9, 12, 13, 14, 15, 16, 17, 18, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Rejected claims 3, 5-7, and 9-10 are drawn to plant host cells and transgenic plants that comprise a construct having a promoter, which is linked to a structural nucleic acid molecule that comprises SEQ ID NO: 1 or the complement thereof which encodes a protein or peptide, which is also linked to a 3' non-translated sequence that functions in said cell to cause termination of transcription.

The rejected claims also include claims 12-20 which are drawn to substantially purified nucleic acid molecules which comprise or consist of SEQ ID NO: 1 or a nucleic acid molecule that has a particular percent identity with SEQ ID NO: 1 (as little as 70% identity, with some claims requiring 100% identity).

The specification discloses over twenty thousand nucleic acid molecules that were isolated from the plant species *Glycine max*. The specification teaches that each one of these molecules may comprise regulatory elements (p. 16), may comprise genes encoding polypeptides or fragments thereof (p. 24) or may comprise introns and/or intron/exon junctions (p. 29). There is no further guidance in the specification, however, to assist one in determining which of these possible characterizations is applicable to instant SEQ ID NO: 1. The specification provides only one specific reference to SEQ ID NO: 1 individually, on page 101 the specification teaches that SEQ ID NO: 1 has 50% identity to a putative POL3 protein from *A. thaliana*. The specification does not, however, disclose what portion of this putative protein has identity with SEQ ID NO: 1. A sequence search by the examiner was unable to confirm this result. There is extensive discussion as to why this teaching in the specification is not sufficient to establish that SEQ ID NO: 1 encodes a POL3 protein in the utility rejection in this office action. That discussion applies here as well. All other discussion in the specification of the potential function

of the disclosed polynucleotide is generic in nature because it refers to all 20,082 nucleic acids disclosed in the specification in mass.

The specification does not provide any specific guidance as to whether SEQ ID NO: 1 comprises regulatory elements, sequence encoding polypeptides, introns, or intron/exon junctions. Given that the specification asserts that instant SEQ ID NO: 1 may include any or all of these, it is highly unpredictable based on the teachings of the specification as to whether or not instant SEQ ID NO: 1 contains or is a gene encoding a structural protein and, likewise, it is highly unpredictable how to use any protein or peptide that may be encoded by SEQ ID NO: 1.

Regarding the potential function of SEQ ID NO: 1, the specification does not provide any specific teaching. The specification discloses over twenty thousand nucleic acid molecules that were isolated from the plant species *Glycine max*. The specification teaches that each one of these molecules may comprise regulatory elements (p. 16), may comprise genes encoding polypeptides or fragments thereof (p. 24) or may comprise introns and/or intron/exon junctions (p. 29). Since all assertions of the function of SEQ ID NO: 1 are given generally for this sequence and over twenty thousand other sequences, none of these statements can be considered specific to SEQ ID NO: 1. Further, the different statements conflict, as it is highly unlikely that the single 394 base pair fragment of SEQ ID NO: 1 at the same time comprises regulatory elements, structural genes, intron and promoter regions. Thus, it is left to one attempting to make and use the claimed products to determine which instant SEQ ID NO: 1 actually is and how it can be used within the constructs claimed.

Considering then, the state of the prior art, instant SEQ ID NO: 1 is a novel sequence. A sequence search by the examiner in a variety of nucleic acid databases did not identify any

sequence in the prior art with greater than 29% identity over the full length of SEQ ID NO: 1. For example, GenBank AF147259 (13 August 1999) provides the sequence of an A. thaliana BAC, and nucleotides 46185-46519 of this sequence have 29% identity with instant SEQ ID NO: 1. This however is an uncharacterized portion of nucleic acid, and even if the homology were exact would not provide any further guidance as to whether instant SEQ ID NO: 1 contains a promoter or promoter elements, or an intron, or a coding sequence.

Furthermore, even if SEQ ID NO: 1 contains a functioning promoter or regulatory element, with regard to claims 12-15, the prior art makes clear that the ability of a promoter to function is highly sequence specific. The art teaches repeatedly that mutations in a critical region of a promoter element can destroy the ability of a construct to function in promotion. For example, Pietrzkowski *et al.* (Experimental Cell Research, 193, 283-290 (1991)) teaches that when synthetic promoters were produced wherein the sequence of an enhancer element was mutated, little to no promotion was observed from the constructs where the promoter was mutated (see for example Figure 6). Chan *et al.* (Plant Molecular Biology 46 :131-141, (2001)) teach that mutation in a critical XXIII element of the GAPB promoter abolished transcription completely (Figure 6), while mutations in other elements did not abolish activity (Figure 6). Thus, it is evident that it is highly unpredictable how promoter elements will respond to even very minor sequences changes. In addition, the order in which promoter elements occur in a construct has an effect on the functionality of the promoter. Omilli *et al.* (Molecular and Cellular Biology, June 1986, p. 1875-1885) teach that the relative arrangement of promoter elements is a critical factor contributing to the activity of the promoter (ABSTRACT, for example).

Without knowing the function of SEQ ID NO: 1 or the protein or peptide encoded by SEQ ID NO: 1, one cannot predict how that function might change with any substation, let alone the extensive substitution allowed by some of the claims. In the absence of a specific and substantial utility for the invention of claim 12, it is unclear what, if any, modifications could be made to the claimed sequence. For example, it would be reasonably clear to a person of ordinary skill in this art that more extensive modification can be made to SEQ ID NO: 1 if it were an intron as opposed to a regulatory element or protein encoding sequence. Without a clear understanding of the use of SEQ ID NO: 1, one of ordinary skill in this art cannot reasonably predict, without undue experimentation, what the effects of any substitution would be.

Thus, having considered the scope of the claims, the teaching in the specification, the guidance in the prior art, the lack of working examples, and the high level of unpredictability with respect to the prior art, it is concluded that it would require undue experimentation to make and use the claimed invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanksley et al. (US 5648599).

Tanksley et al teach a transformed plant cell and transformed plants comprising said cells, wherein said cells comprise an exogenous promoter, a structural gene, and a termination sequence (see the claims, for example). Regarding claims 10-19, the nucleic acids taught by Tanksley et al. comprise nucleic acid sequences that have the required identity to "a nucleic acid sequence" of SEQ ID NO: 1. These claims are anticipated by Tanksley et al. insofar as they require the identity be relative to only "a nucleic acid sequence of" SEQ ID NO: 1. The use of the indefinite article "a" to modify the required nucleic acid sequence is interpreted to require that the claimed molecules only have display identity to any portion that is "a" part of SEQ ID NO: 1, including a single nucleotide, as opposed to SEQ ID NO: 1 in its entirety. Thus, the molecules taught by Tanksley et al. are considered to have the constructs claimed insofar as they comprise molecules with identity to "a" nucleic acid sequence of SEQ ID NO: 1. Amendment of the claims to read, for example, "having between 100% and 70% identity with the nucleic acid sequence of SEQ ID NO: 1 or the complement thereof" would overcome this rejection.

9. Claims 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene Catalog (1997, p. 95).

Stratagene teaches a mix of substantially purified molecules having therein every possible hexamer sequence. Regarding claims 10-20, the nucleic acids would include a variety of different six nucleotide fragments that consist of fragments having identity to "a nucleic acid sequence" of SEQ ID NO: 1. These claims are anticipated by the hexamar mix insofar as they

require the identity be relative to only "a nucleic acid sequence of" SEQ ID NO: 1. The use of the indefinite article "a" to modify the required nucleic acid sequence is interpreted to require that the claimed molecules only have display identity to any portion that is "a" part of SEQ ID NO: 1, including a single nucleotide, as opposed to SEQ ID NO: 1 in its entirety. Amendment of the claims to read, for example, "having between 100% and 70% identity with the nucleic acid sequence of SEQ ID NO: 1 or the complement thereof" would overcome this rejection.

Response to Remarks

Applicant requests reconsideration of the rejection for lack of utility in light of additinal evidence and arguments provided in the response. First, it is to be noted that the "evidence" provided is in the form of attorney arguments, search results from public databases, and non-patent literature. No evidence in the form of a declaration or affidavit has been provided. The papers provided by Applicant, which include amendments to the claims, remarks, an IDS, and a paper with appendices under the heading "Information Statement" have all been considered. A signed 1449 is included with this office action.

The results of the BLASTX report provided on page 6 of the response, and referred to in the specification is discussed in the utility rejection in this office action. For the reasons stated in the rejection, the arguments based on the BLASTX report are not persuasive.

On page 6 of the response and in the response applicant refers to a "confirmatory BLASTX analysis" confirms that SEQ ID NO: 1 has highly significant correlations with sequences encoding proteins having polymerase activity. The search was performed 11/12/2008. There is no indication in the search that any of the results given in the search were available in the prior art. The first record in the list, for example, is dated February 7, 2006 (see enclosed

NCBI record ABC49721.1). Further, there is no assertion in the specification that instant SEQ ID NO: 1 encodes a polypeptide that "has polymerase activity," there is only a teaching in the specification that a portion of a polypeptide encoded by SEQ ID NO: 1 has identity with a portion of a polypeptide that has been identified as a "putative" POL3. Applicant has not established a utility for the claimed invention such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public*." In re Fisher, 421 F.3d at 1371, emphasis in original. The rejection is maintained, and modified to address the remarks and the amendments to the claims.

Regarding the enablement rejections, in part (A) applicant argues that the claims are enabled because the utility rejection has been overcome. Since the arguments regarding the utility rejection were not persuasive, nor is this argument. The rejection is maintained.

(B) Applicant argues that the enablement rejection of claims 3, 5 to 7, 9, and 10 should be withdrawn in view of the amendments to recite that the cell and plant comprise "a structural nucleic acid that comprises SEQ ID NO: 1 or the complement there of, which encodes a protein." However, for the reasons stated in the rejection, and affirmed by the Board of Appeals, the rejection is maintained.

(C) Applicant states that the examiner admits that SEQ ID NO: 1 has homology to a POL3 enzyme. To the contrary, the examiner repeats only the teaching of the specification-namely that SEQ ID NO: 1 has 50% identity to a putative POL3 protein, with putative being a critical word in that teaching. This teaching and the reasons for its insufficiency are discussed in the enablement rejection in this office action. The rejection is maintained.

The rejections under 102(b) have been reinstated to address remaining problematic broad claim language. Amendments to overcome the rejection are suggested.

Conclusion

10. No claim is allowed.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Tuesday or Wednesday, from 9:00 AM until 4:30 PM, and Thursday afternoon from 12:30 PM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Juliet C. Switzer/
Primary Examiner
Art Unit 1634

February 12, 2009

This is a result from a sequence search showing instant SEQ ID NO: 1 aligned to a gene encoding a P. coccineus putative POL3-like protein. The gene is listed in GenBank as accession AF325187. Below is a portion of the text of the record, followed by the alignment. In the alignment, instant SEQ ID NO: 1 is the top line (Qy) and the prior art gene is the bottom line (Db). The text of the record teaches that the mRNA includes nucleotides 28-595, 758-837 and 1270-1653 of the sequence (see bold portion of the "FEATURES" section). Instant SEQ ID NO: 1 aligns with the complement of nucleotides 1216-1553 of the record, which is a portion within the portion that makes up the coding sequence (i.e. the mRNA).

```
 AF325187/c
LOCUS       AF325187               4921 bp    DNA     linear   PLN 05-DEC-2001
DEFINITION  Phaseolus coccineus putative POL3-like reverse transcriptase
            (POL3-like) and suspensor-specific protein (G564) genes, complete
            cds.
ACCESSION   AF325187

FEATURES             Location/Qualifiers
     source          1. .4921
                     /organism="Phaseolus coccineus"
                     /mol_type="genomic DNA"
                     /cultivar="Hammond's Dwarf Red Flower"
                     /db_xref="taxon:3886"
                     /tissue_type="embryo"
                     /dev_stage="6 days post-pollination"
     gene            <28. .>1653
                     /gene="POL3-like"
     mRNA            join(<28. .595,758. .837,1270. .>1653)
                     /gene="POL3-like"
                     /product="putative POL3-like reverse transcriptase"
     CDS             join(28. .595,758. .837,1270. .1653)
                     /gene="POL3-like"
                     /note="similar to Arabidopsis thaliana POL3"
                     /codon_start=1
                     /product="putative POL3-like reverse transcriptase"
                     /protein_id="AAK14317.1"
                     /db_xref="GI:13173146"
                     /translation="MVLPPQVENLLSEFEDLFSQEGPIGLPPLRGIEHQIDFIPGASL
                     PNRPPYRTNPEETKEIESQVQDLLEKGWVQKSLSPCAVPVLLVPKKDGKWRMCCDCRA
                     INNITIKYRHPIPRLDDMLDELHGSTLFSKIDLKSGYHQIRIKEGDEWKTAFKTKFGL
                     YEWLVMPFGLTNAPSTFMRLMNHTLRDCIGFIVNQKGVHVDPEKIKAIREWPTPQNGQ
                     HKLNKRHAKWMEPLEQFPYVIKYKKGSTNIVADALSRRHTLFSKLGAQILGFDHIREL
                     YQEDQELSSIYAQCLHRAQGGYYVSEGYLFKEGKLCIPQGTHRKLLVKESHEGGLMGH
                     FGVDKTLDF"


  Query Match           40.5%;  Score 159.4;  DB 8;  Length 4921;
  Best Local Similarity   66.9%;  Pred. No. 2.3e-34;
  Matches  226;  Conservative    0;  Mismatches  112;  Indels    0;  Gaps    0;

Qy          1 AGCTTTCCCTCTTTGAACAAATACCCCTCAGCCAAATAGAATCCATCTTGGGCCTTTTTC 60
              || ||||| ||||| || | ||| ||||| | || |||| | ||  |||| ||  | |
```

```
Db       1553 AGTTTTCCTTCTTTAAAAAGATATCCCTCGGACACATAGTAACCTCCTTGTGCTCTATGT 1494

Qy         61 CCACAACTCTCATAAATGGGAGACAAATGTTCATCTAAAGCATACAAGTCCCTAATATTA 120
                |||     ||||| |||||  ||||  | || |||||     ||| |  || || ||| |
Db       1493 AGACATTGGGCATAGATGGATGACAGATTCTTGATCTTCTTGATAAAGCTCTCTTATGTGG 1434

Qy         121 TCAAATCCTAAAATTTGAGCTCCTAGGGAGCAAAACAATGTGTGTCTCCTAGAGAGGGCA 180
               |||||||| | ||||||| || ||||||      |||| |  ||||| |  ||||| || |||
Db       1433 TCAAATCCAAGAATTTGGGCACCTAGTTTTGAAAAGAGAGTGTGCCGTCTAGAAAGAGCA 1374

Qy         181 TCAGCTACCACATTTGTTTTCCCTTTTGTATTTGATAACATATGGAAATTGCTCTAGG 240
               || || || | ||| ||  | || || ||||||||||| ||||| |||||||| || ||
Db       1373 TCGGCCACTATATTGGTGCTCCCTTTCTTGTATTTGATGACATAAGGAAATTGTTCAAGA 1314

Qy         241 TACTCTACCCATTTTGCATGCCTCTTGGTTAACTTGCTTTGCCCTCTAATGTACTTAAGT 300
                | || | |||||| ||||| |||||  | | ||||  ||| ||  | |  || || |
Db       1313 AATTCCATCCATTTAGCATGTCTCTTATTGAGCTTGTGTTGGCCCTTTAAATATTTTAAA 1254

Qy         301 GATTGATGATCACTATGAATGACAAATTCCTTGGAAAC 338
               || |  |||||||||| ||  | || | ||| |  ||
Db       1253 GACTCGTGATCACTATGGATANCCAAATTCTTTGGGAC 1216
```